Scientific & Regulatory Consultants, Inc.

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W. ROBERT MACDONALD

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Scientific & Regulatory Consultants, Inc. provides a full range of regulatory services for the antimicrobial industry. Our consultants' insight provides scientifically-sound, cost-effective, and timely solutions to routine and complex issues facing our clients. Our collective knowledge base includes experience in industry, laboratories and with government entities. For more information about Scientific & Regulatory Consultants, Inc. visit our website at www.srcconsultants.com

PROFESSIONAL EXPERIENCE

Scientific & Regulatory Consultants, Inc., Columbia City, IN 1998 - Present

Vice-President, Regulatory Affairs (2014 – Present); promotion
Senior Consultant (1998 – 2014)

- Specializing in scientific and regulatory consulting services for antimicrobial products from inception to commercialization
- FDA/EPA topical antimicrobials and regulations affecting them
- Industry regulatory changes and inspection trends
- Research and data compilation
- Technical Writing; Product positioning options based on claims, competitive offering and market assessment
- Antimicrobial market trends
- Client work plan formulation

Ecolab, Inc. (formerly Huntington Laboratories, Inc.), Huntington, IN 1979 - 1998

RSP Private Label Packaging Manager (1989 – 1998)

- Manage sales, and marketing of private label topical antimicrobial products, responsible for $5MM in sales
- Developed prototype literature and labels for RSP (topical antimicrobials) line, including CHG, PCMX, Iodophor, Alcohol, and Triclosan products
- Formula customization
- Established territories and sales call procedures
- Provided broad-based client technical support
- Established quarterly sales quotas
- Identified new business pursuits

Regulatory Affairs Manager (1981 – 1989)

- Antimicrobial product EPA Registration
- FDA product compliance
- Maintained current knowledge of regulations and activities in the market to advise management of potential effect on corporate client products

- Development and presentation of regulatory policy and procedures, instructional seminars to sales and internal staff; assured regulatory compliance of labels, literature and collateral materials
- Negotiate with regulatory agencies to obtain product registration
- Ensure compliance with State, Federal, and Canadian regulations

Microbiology Manager (1980 – 1981)

- Responsible for EPA and FDA products with registered claims
- Development of supportive testing for new antimicrobial product registration
- EPA Use-Dilution and AOAC Germicidal Spray Test
- Bacterial culture preparation and maintenance
- Healthcare Personnel Handwash (HCPHW) studies and glove juice testing
- Sterility and Preservative Testing on topical formulations
- Daily microbial water analysis
- Development of efficacy test data for submission to regulatory agencies
- Collaborated with EPA Laboratory (Beltsville, MD) on AOAC Use-Dilution Test

Quality Assurance Chemist (1979 – 1980)

- Responsible for quality testing of product batch from physical chemistry aspect
- Tested raw materials for specification compliance
- Performed problem solving for correcting deviations from specifications

EDUCATION

B.S. in Biology, Manchester College (now Manchester University), North Manchester, IN; 1978

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

International Association for Food Protection (IAFP)
Regulatory Affairs Professional Society (RAPS)
Canadian Consumer Specialty Products Association (CCSPA)

CORPORATE PROFESSIONAL AFFILIATIONS

American Chemistry Council (ACC) Biocide Panel
British Association of Chemical Specialties (BACS)
Household & Commercial Products Association (HCPA) (Formerly CSPA)
International Sanitary Supply Association (ISSA)
Personal Care Products Council (PCPC)

PROFESSIONAL DEVELOPMENT

U.S. Environmental Protection Agency (EPA)

Antimicrobial Data Requirements 40 CFR Part 158, Subpart W:
- Introduction and Overview; 07/16
- Mammalian Toxicology Data Requirements for Antimicrobial Pesticides; 07/16
- Environmental Fate & Transport; 08/16
- Antimicrobials Used in Cooling Water Systems; 08/16

Smart Label Webinar; 12/15

Greening Operation Series: Regulatory Update-Antimicrobial Labeling Update from the EPA; 07/09

California Department of Pesticide Regulation (CDPR)

California Prop 65 Update; 11/12

U.S. Food and Drug Administration (FDA)

Dietary Supplements: How to Deal with New Criminal, Civil Enforcements; 05/17

How to Conduct Effective Quality Audits; 04/17

Premarket Notification Requirements Concerning Gowns Intended for Use in a Health Care Setting; 01/16

Regulatory Education for Industry (REdI); Focus on cGMPs & FDA Inspections; 07/15

Overview of Medical Device Data Systems, General Wellness Devices, and Medical Device Accessories; 02/15

Regulatory Education for Industry (REdI) Conference; 09/17, 05/15, 09/14, 09/12

Food, Drug & Device Facility Inspections: Lessons from FDA, the Minnesota Department of Agriculture, and Industry Teleconference; 11/12

Clinical Trials and Electronic Submissions; 09/11

SPL R4 Training Session 58 – Bulk Ingredient/Bulk Product SPL; 03/11

SPL R4 Training Session 57 – OTC Drug Product SPL; 03/11

Drug Establishment Registrations, Drug Listings and the FDA Electronic Submissions Gateway; 10/09

Preparing Electronic Drug Est. Registration and Drug Listing Submissions; 06/09, 05/09, 04/09

510(k) – Essentials of Gaining FDA Marketing Clearance; Bannick Consulting, LLC.; 03/09

Health Canada Pest Management Regulatory Agency (PMRA)

New Versions of PMRA's On-Line Forms; 07/13

RPC PMRA Notification Non-Notification; 10/12

Natural and Non-Prescription Health Products Directorate (NNHPD)

The Consumer Health Products Framework; 01/15

American Chemistry Council (ACC)

Biocides Panel Meeting with PMRA; 07/10

American Society of Agronomy

Definitions and Regulatory Requirements; 07/15

American Management Association (AMA)

Real Influence: Persuade Without Pushing and Gain without Giving In; 01/13

iPad at Work; Tools for Business Productivity and Time Management; 10/12

Association for Professionals in Infection Control and Epidemiology (APIC)

Infection Prevention: Improving Outcomes, Saving Lives; 04/12
Role of Surfaces in the Transmission of Emerging Healthcare-Associated Pathogens: Norovirus, Clostridium Difficile and Acinetobacter Spp.; 02/12
Antimicrobial Associated Risk and Clostridium Difficile; 12/08
The Latest from the Centers for Disease Control and Prevention on Clostridium Difficile; 12/08
Clostridium Difficile Prevalence Research Highlights; 12/08

American Society for Testing & Materials (ASTM)

Committee Week; 04/14

Bergeson & Campbell, P.C.

Border Security: EPA's Increased FIFRA Import Enforcement Initiative; 03/15

Canadian Consumer Specialty Products Association (CCSPA)

Annual CCSPA/Federal Government Interface; 05/17, 09/16, 04/16, 04/15, 09/13, 04/13, 04/10, 04/09, 03/07, 03/05
Regulated Products Committee (RPC) Bilateral Meeting with Therapeutic Products Directorate (TPD); 11/13, 05/10
CCSPA/PMRA: Treated Articles; 06/11

Canadian Pesticide Regulation Course (CPRC)

Training on policies, submissions, and required data; 02/08

CDRH, Division of Industry and Consumer Educations (DICE)

CDRH Industry Basics Workshop; 11/14

Compliance4All

21 CFR Part 11 – Compliance for Electronic Records and Signatures; 04/17
GMP Perspectives on Working with Contracting Laboratories; 11/14

Consumer Healthcare Products Association (CHPA)

2008 cGMPs FDA/Industry Workshop; 08/08

Consumer Product Safety Council (CPSC)

A to Z & Beyond; 06/14

FDA News

FDA's New Food Safety Regulations, Part 1; 08/17
Writing Effective SOPs; 04/17
Promotion of Drugs, Devices, and Biologics Using Social Media; 02/17
Spreadsheet Validation 2016; Tools and techniques to Meet FDA Requirements
Form 483 and Warning Letter Responses; 12/16

Preparing for an FDA Preapproval Inspection; 11/16

FDA Strategies, LLC.

FDA's Current Priorities; 08/13

The Food and Drug Law Institute (FDLI)

Sunscreen Innovation Act; 01/15

Gladieux Consulting

Powerful Presentation & Verbal Communication Skills; 05/09
What Your Words Say About You and Your Team: Business Writing; 04/09

Global Compliance Panel

Meeting FDA requirements for OTC Drug Labeling; 12/13

Global Strategies

An Overview of Brazil's Cosmetic Regulations; 07/13

Household & Commercial Products Association (HCPA) (Formerly CSPA)

Discover the New Consumer Product Ingredients Dictionary; 11/17
Eleventh Antimicrobial Workshop; 03/15
Consumer Product VOC Compliance; 10/14
What Is a Misbranded Product? Webinar; 10/10
The CPSC from A to Z….and Beyond; 09/10
What Every Active Ingredient Supplier and Formulator Need to Know About Supplemental Distributor Agreements; 08/10
To amend or not to amend? Will someone please explain PRN 98-10 to me!; Webinar; 10/09
Annual and Mid-Year Meetings; 05/15, 12/14, 05/13
CSPA Consumer Product Labeling Workshop; 10/08
CSPA Workshop on Importing Pesticide Products; 06/08

Indiana University – Purdue University – Fort Wayne (IPFW)

Professionalism and Etiquette for Business; 10/17
The Building Blocks of Effective Messages; 08/17

Institute for In Vitro Sciences (IIVS)

An In Vitro Ocular Hazard Testing Strategy for EPA Registered Antimicrobial Cleaning Products; 11/12

International Association for Food Protection

Overview of the Safe Food for Canadians Act: CFIA Food Safety Regulatory Modernization; 11/13

The International Center

Understanding Japanese Business Culture; 02/13

The Jackson Laboratory

Understanding the Landscape of the Skim Microbiome and Potential Applications for Personal Care Products; 06/17

The Microbiology Network

Microbiological Laboratory Investigations; 08/12

Review of Microbiological Involvement in Product Recalls; 02/12

Topics in Pharmaceutical Microbiology, 08/10

NSF International

Annual Steering Committee Meeting; 10/16, 10/14, 10/13, 11/10, 10/07, 10/03, 09/02, 07/01

Nonfood Compounds and Proprietary Substances Registration Program; 10/08

National Pesticide Information Retrieval System (NPIRS)/Purdue University

ALSTAR Training; 09/10

National Training Seminars

8 Steps for Highly Effective Negotiation; Letting the Other Person Have Your Way; 04/15

How to Facilitate Meetings Effectively; 02/15

Business Writing Essentials: Make Your Point Clearly & Concisely; 02/15

Mastering Microsoft Excel Macros; 06/14

How to Manage Priorities & Time; 08/13

Personal Care Products Council (PCPC)

2016 Science Symposium; 10/16

Member Briefing; 04/17, 01/16

GMP Workshop; 06/17, 04/15

Australian Regulatory Requirements for Cosmetic Products; 08/14

Personal Care Products Council – 2011 Legal & Regulatory Meeting; 05/11

Disruption and Personal Care Products – Science and Regulatory Developments; 07/10

Cleaning and Sanitization for the Manufacture of Personal Care Products; 11/08

Reglaw Regulation Week Broadcasts

OSHA- Hazard Communication Standard; 10/13

Regulatory Affairs Professionals Society (RAPS)

Natural Health Product (NHP) Licensing in Canada: Moving Forward-Updates, Initiatives and Challenges; 10/09

Pre-IND Meeting Success: Know and Remove Roadblocks to Trial Approval; 10/09

RAPS Preparing Compliant eCTD Submission Workshop; 05/09

Recall or Not to Recall Webcast; 02/09

Scientific & Regulatory Consultants, Inc.

6(a)(2) Training; 07/16

EPA 101: Submission Review, Training, and Overview; 06/16

NSF Overview; 02/16
Telephone Etiquette; 02/16
NOA (Notice of Arrival); 06/15
CRP (Child Resistant Packaging); 05/14
Training - OECD bactericidal method and results of 2011-12 BEAD Collaborative; 10/12

SHEA

The Fifth Decennial International Conference on Healthcare Associated Infection; 03/10

Society of Quality Assurance (SQA)

Good Clinical Laboratory Practices; Coloring Outside the Lines; 11/14
The US EPA Agricultural Field Trials – An Overview; 06/14
Good Clinical Laboratory Practices (GCLP) Auditing; 10/12

Steptoe & Johnson LLP

Advertising Class Actions: The Latest Litigation Fad; 11/13

Thompson Publishing Group

An In-Depth Panel Discussion: Dealing with Potential FDA Enforcement; 03/12
Online Advertising: Ensuring Compliance as DDMAC Steps Up Enforcement; 08/09

Washington Legal Foundation

FDA Goes Astray on Device Oversight: Proposed Guidance on 510(k) Review, Adverse Events Reporting, and Results; 10/13

Waters Corporation

Why is Electronic CDS Data a Major Data Integrity Concern for Regulators?; 04/17

Webber Training

Contamination of the Ward Environment: The Importance of Hand Hygiene When Leaving the Patient; 12/12
Surface Disinfection and Microbial Resistance; 12/12
The Hand is Quicker than a Sneeze in the Spread of Disease; 09/12

West Coast Quality Training Institute

"Practical Approach" Seminar; Introduction to Good Laboratory Practice Regulations; 07/09
"Practical Approach" Seminar; Advanced GLP Issues; 07/09

Wright Alliance

Toxicology 101: General Principles and Applications for Assessing Human Health Effects of Chemical Substances; 02/13
Biocide Product Directive and REACH; 08/08

PUBLICATIONS & PRESENTATIONS

PRESENTATIONS

MacDonald, B. 2014. “Distributor Considerations”, Regulators/Labeling and “What’s in a Claim”, Scientific & Regulatory Consultants, 2014

MacDonald, B. 2012. “6(a)(2) Reporting Guidelines”, Scientific & Regulatory Consultants, 2012